UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,175	02/16/2006	Frederic Henot	37998-237505	1959

26694 7590 04/28/2008

VENABLE LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
WEN, SHARON X	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
04/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,175	HENOT ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-17 and 22-29* is/are pending in the application.

4a) Of the above claim(s) *24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *15-17, 22-23 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 01/25/2008, has been entered.

Claims 1-14 and 18-21 have been canceled.

Claims 15-17, 22-29 are pending.

Claims 24-26 have been withdrawn from further consideration under 37 CFR § 1.142(b) as being drawn to non-elected Groups and/or Species.

Claims 15-17, 22-23 and 27-29 are currently under examination as they read a pharmaceutical composition comprising grass allergen as the elected species.

2. This Action will be in response to Applicant's Arguments/Remarks, filed 01/10/2008.

The rejections of record can be found in the previous Office Action.

Claim Rejections - 35 USC § 112, second paragraph

3. The previous rejection under 35 USC 112 second paragraph has been withdrawn in view of Applicant's amendment, filed 01/25/2008.

Claim Rejections - 35 USC § 102

4. The previous rejection under 35 USC 102(b) as being anticipated by Pradalier et al. has been withdrawn in view of Applicant's amendment, filed 01/25/2008.

5. The previous rejection under 35 USC 102(b) as being anticipated by McKnight et al. has been withdrawn in view of Applicant's amendment, filed 01/25/2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 15-17, 22-23 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pradalier et al. (Allergy 1999, 54:819-828) in view of Ball et al (U.S. Patent 6,559,120, reference of record) Ćirković et al. (Allergy 1999, 54:128-123, reference of record), Malley (U.S. Patent 4,215,036, reference of record) and Marx (U.S. Patent 5,898,037, reference of record).

Applicant's arguments, filed 01/25/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

In response to Applicant's assertion that the teachings of Ćirković and Malley do not remedy the deficiency of Pradalier, the following is noted.

Teachings of Pradalier is reiterated herein for Applicant's convenience.

Pradalier et al. teach a pharmaceutical composition comprising grass allergens wherein the composition is in a sublingual formulation (see entire document, in particular, page 819 Methods, page 821 sections under Allergen preparations and Treatment).

The reference teaches making the pharmaceutical composition comprising grass allergens in the range of 0.001 to 1000 µg or 1 to 100 µg (see page 821, section under Treatment). The reference discloses that cumulative allergen doses in the active treatment group was about 11,000 IF corresponding to 0.935 mg or 935 µg; and that single sublingual tablet contains 100 IR, or 9.35 µg of allergen. Therefore these amounts of allergen taught by the reference anticipate the ranges recited in claims 16-17.

Although the reference is silent on the substance (i.e. grass pollen) being a peptide (claim 19), grass allergens are well known to be proteins/peptides by the ordinary artisan in the art at the time of the invention was made as evidence by Ball et al. (see column 1, lines 62-65). Therefore the grass pollen taught by Pradalier et al, under the broadest reasonable interpretation, reads on peptides.

Similarly, under the broadest reasonable interpretation, a composition formulated for sublingual administration as taught by the reference would also be in buccal or enteric formulation (claims 28-29).

The teaching of Pradalier *differs* from the newly amended claim in that it does not teach "**peptides having a molecular weight of less than 10 kDa**". As stated in the previous Office Action, mailed 07/25/2007, it was well known in the art at the time of the invention to make low-molecular weight allergens in a pharmaceutical composition as demonstrated by Malley, wherein the grass allergen has been modified to have molecular weight of less than 10 kDa (reference of record, see, e.g., column 1, lines 56-60).

In particular, one of ordinary skill in the art would have been motivated to made low-molecular weight allergen because of the teaching by Ćirković stating that low molecular weights make the allergen able to cross biological membrane thus suitable for sublingual administration (page 129, left column, paragraph 3) and that the modification procedure used to make low molecular weight allergen yields allergens of good performance in immunotherapy (page 134, left column, lines 1-2).

Given the above, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to make a pharmaceutical composition comprising grass allergen such as orchard grass pollen as taught by Pradalier et al. and modify the allergen to obtain a low molecular weight of less than 10 kDa as taught by Ćirković et al. and Malley, especially in the absence of evidence to the contrary.

In response to Applicant's argument that Marx does not teach compositions for treating allergic reaction, the following is noted.

Marx teaches nucleoside triphosphates are well known adjuvants used in immunotherapy associated with allergic reactions as evidence by Marx (see entire document, in particular, Detailed Description of Preferred Embodiments). Specifically, Marx teaches that ATP, a nucleoside triphosphate, is a preferred adjuvant in a composition suitable for treating allergic skin condition which reads on allergic reaction as *a species reads on a genus* (see column 5, lines 4-10 and lines 52-55).

Given the teaching by Pradalier on the pharmaceutical composition comprising grass allergen for treating allergic reaction and the teaching by Marx on using ATP as an adjuvant for immunotherapy associated with allergic reaction, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to make a pharmaceutical composition comprising grass allergen and nucleoside triphosphates such as ATP for immunotherapy associated with allergic reaction.

Furthermore, given the teaching by Pradalier et al. that the aim of the sublingual immunotherapy with grass allergens is to elicit IgE and IgG production (page 827, right column, second paragraph), and that the teaching by Marx that ATP is a preferred adjuvant for treating allergic conditions (see column 5, lines 4-10 and lines 52-55), one of ordinary skill would have been motivated to add nucleoside triphosphates such as ATP in a pharmaceutical composition comprising grass allergen for sublingual immunotherapy.

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

Conclusion

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./
Examiner, Art Unit 1644
April 15, 2008

/Eileen B. O'Hara/

Supervisory Patent Examiner

Art Unit 1644